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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE APPLICATION NO. 07/25/2003 Peter B. Vander Horn 020130-001420US 2975 10/627,592 **EXAMINER** 20350 7590 06/02/2005 TOWNSEND AND TOWNSEND AND CREW, LLP HUTSON, RICHARD G TWO EMBARCADERO CENTER ART UNIT PAPER NUMBER **EIGHTH FLOOR** SAN FRANCISCO, CA 94111-3834 1652

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/627,592	VANDER HORN, PETER B.
	Examiner Richard G. Hutson	Art Unit
The MAILING DATE of this communication ap	1	orrespondence address
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1)⊠ Responsive to communication(s) filed on <u>07 January 2005</u> .		
·_	is action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) ⊠ Claim(s) 1-16 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) □ Claim(s) is/are allowed. 6) □ Claim(s) is/are rejected. 7) □ Claim(s) is/are objected to. 8) ⊠ Claim(s) 1-16 are subject to restriction and/or election requirement.		
Application Papers		
9)☐ The specification is objected to by the Examiner.		
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
Attachment(s)		·
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	

DETAILED ACTION

The examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1652, Examiner Richard Hutson Ph.D.

Claims 1-16 remain pending.

Election/Restrictions

It is noted that the previous restriction requirement sent to applicants on 1/7/2005 was in error, indicating that claim 6 is grouped in both Group I and Group II. It is further noted that applicants elected with traverse Group I, claims 1-6 in the paper of 3/10/2005. Claim 6 should have been properly grouped in Group II only.

Thus, the previous restriction requirement has been modified as below.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a method of creating a hybrid protein, classified in class 435, subclass 91.1.
- II. Claims 6-10, drawn to a nucleic acid library encoding hybrid proteins, classified in class 536, subclass 23.2.
- III. Claims 11-16, drawn to a hybrid protein, classified in class 435, subclass 183.

Inventions I and inventions II and III are related as process of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of

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Group I can be used to make the materially different products of the library of Group II and the proteins of Group III. Further the library of Group II and the proteins of Group III can each be made by another materially different processes of chemical synthesis.

The library of nucleic acid molecules of Invention II is related to the hybrid protein of Invention III by virtue of encoding the same. The nucleic acid molecules have utility for the recombinant production of hybrid protein in host cells. Although the nucleic acid molecules and hybrid protein are related, since the nucleic acid molecule encodes the specifically claimed hybrid protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis. Further, each nucleic acid molecule of the library may be used for processes other than the production of the protein, such as in a nucleic acid hybridization assay, while the library itself can be used as a template for polymerase-mediated amplification in vitro.

Because these inventions are distinct for the reasons given above and the search required for Groups I-III are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call made to Jean Lockyer on 5/26/2005, confirmed applicants election of group I, in spite of claim 6 being limited to Group II.

It is further noted that this application contains claims directed to the following patentably distinct species of the claimed invention: methods of creating hybrid proteins having any common biological activity and methods of creating hybrid proteins wherein the parent proteins are any enzyme.

Applicant is required under 35 U.S.C. 121 to elect a single specific species of biological activity and single specific enzyme for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 2 of elected Group I are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard G Hutson, Ph.D. Primary Examiner Art Unit 1652

rgh 5/27/2005